Exhibit #1

K072108

510(k) Summary

AUG 3 1 2007

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:		Tecnimed srl, 12 P.le Cocchi, 21040 Vedano Olona (VA) Italy
Official contact person for all correspondence:		Francesco Bellifemine E-mail: info@tecnimed.it
Date Prepared:		July 17, 2007
Device Name:		**Thermofocus 0700 series, Thermofocus 0800 series, Thermofocus 0900 series, Thermofocus 01500 series.**
Generic name of the device:		Clinical Electronic Thermometer
Classification of new device:		Class II
Classification Panel:		General Hospital
Product Code and CFR Regulation Number:		FLL and 21 CFR 880.2910
Predicate Device Name and 510(k) Number:		THERMOFOCUS 0800, 0900, 01500 AND 0700 SERIES K033790

Description of Device:

Thermofocus devices belonging to the 0800, 0900, 01500, 0700 series are hand-held and battery-operated thermometers. They take skin temperature mainly in the middle of the forehead, on the navel, neck or under the armpit. The Thermofocus devices use the principle of surveying the natural emission of infrared thermal radiation from all objects, including the human body. Thermofocus thermometers take temperature at distance, without any contact with the patient.

The modified devices incorporate improvements to the thermometers calibration capability and also include other minor "user-friendly" improvements. Specifically, these modifications include:

Comparison of Device Technological Characteristics to Precedent Device:

Precedent Models	New Models
20-30 minute time frame for the device to be stabilized in a new environment.	The user can choose between three different calibration options depending on the model to lessen the amount of time for the stabilization of the thermometer.
Backlighting of the display was not available.	Backlighting of the display is now available.
No option to disable the home button.	In the hospital versions, it is possible to disable the "home" button.
Toggle between settings using 2 buttons.	Toggle between settings using one button.
In the precedent versions, the display of the model 0700 turned off after 20 seconds of no use. While in all the other models the display remained on.	In the new models, it is possible to choose the display always on or always off when not in use. It is also possible to set models 0800, 0900 and 01500 so that the display can turn off after 20 seconds.
Protective cap and memory button on some models	Protective cap and memory button available on all models.

Intended Use:
Thermofocus 0700, 0800, 0900, 01500 series are infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages.

Non-Clinical /Clinical Testing
Performance tests were not required as the modified devices are essentially equivalent to previously cleared predicate devices. Certain performance tests were conducted as part of the risk analysis and demonstrated acceptable results for devices safety and effectiveness.

Both devices meet the ASTM E1965-98 *Standard for Infrared Thermometer for Intermittent Determination of Patient Temperature,* as far as this standard applies to them.

Conclusion:
We have demonstrated that the new Themofocus 0700, 0800, 0900, 01500 series are as safe and effective as our predicate device based on performance testing results as well as the risk analysis supplied with this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tecnimed S.R.L.
C/O Ms. Maria F. Griffin
Official Correspondent
Mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

AUG 3 1 2007

Re: K072108
Trade/Device Name: Thermofocus 0800 Series, Thermofocus 0900 Series, Thermofocus 01500 Series, Thermofocus 0700 Series
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 31, 2007
Received: August 2, 2007

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

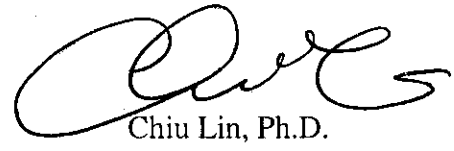
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not Assigned as of this time

Device Name: Thermofocus Professional 0800 series, Thermofocus 0900 series, Thermofocus 01500 series, Thermofocus 0700 series

Indications for Use:
Thermofocus 0800, 0900, 01500, 0700 Series are infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages.

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072108